JUL 2 8 2000

K001388

510(k) Summary
Dideco Data Master Perfusion System
(per 21 CFR 807.92)

1. SPONSOR

Dideco S.p.A.
Via Statale, 12 Nord, 86
I-41037, Mirandola (MO) Italy

Contact Person: Luigi Vecchi
Telephone: 011-39-535-29811

2. DATE PREPARED May 1, 2000

3. DEVICE NAME

Proprietary Name: Data Master Perfusion Monitoring System
Common/Usual Name: On-line perfusion monitor
Classification Name: Blood gas monitor, automatic hematocrit analyzer, electronic thermometer

3. PREDICATE DEVICES

3M CDI-500 (K972962)
3M CDI-400 (K890113)
Medtronic Biotrend (K954501)
Medtronic MX2 Saturation and Hematocrit System (K910421).

4. DEVICE DESCRIPTION

The Data Master is an active or battery-powered, microprocessor-based device used with disposable sensor elements for the purpose of monitoring arterial pO_2, temperature, and venous Sat% or Sat_v%, temperature, hematocrit, as well as auxiliary temperature, e.g., heat exchanger input H_20 temperature.

5. INTENDED USE

The Data Master Perfusion Monitoring System is a cardiopulmonary bypass monitoring system (instrument, probes, and connectors) intended for continuous on-line monitoring of the extracorporeal partial pressure of oxygen, oxygen saturation, hematocrit, and temperature. Measurements performed by the Data Master are intended to supplement and not replace regular laboratory determinations of partial pressure of oxygen, oxygen saturation, and hematocrit.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

Dideco S.p.A. makes this claim of substantial equivalence based on the intended use, design, operational and technological characteristics, materials of construction, and principles of operation. A side-by-side comparison of the Data Master characteristics with the cited predicate devices was provided.

7. PERFORMANCE TESTING

The Data Master Perfusion Monitoring System was tested and demonstrated conformance with internationally recognized consensus standards and with specifications. Testing included electrical safety, electromagnetic compatibility, software verification and validation, and performance testing. A side-by-side test of the Data Master and CDI 400 demonstrated equivalent results for arterial temperature, venous temperature, arterial pO_2, and venous saturation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 8 2000

DIDECO
C/O MDCI
Rosina Robinson, RN, Med, RAC
Senior Staff Consultant
49 Plain Street
North Attleboro, MA 02760

Re: K001388
Dideco Data Master Perfusion Monitoring System
Regulatory Class: II (two)
Product Code: DRX
Dated: May 1, 2000
Received: May 2, 2000

Dear Ms. Robinson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial

equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K001388

Device Name: Dideco Data Master (Data Master)

Indications For Use:

The Data Master Perfusion Monitoring System is a cardiopulmonary bypass monitoring system (instrument, probes, and connectors) intended for continuous on-line monitoring of the extracorporeal arterial partial pressure of oxygen, venous oxygen saturation, hematocrit, and temperature (arterial and venous). Measurements performed with the Data Master are intended to supplement and not replace regular laboratory determinations of partial pressure of oxygen, oxygen saturation, and hematocrit.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K001388

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)